MAR 1 7 2006

K060267

EXHIBIT 2

510(k) Summary

Implant Logic Systems, Ltd.
76 Spruce St.
Cedarhurst, NY 11516
Tel 516-295-1121
Fax 516-295-2992
www.implantlogic.com
Contact: Michael Klein, DDS, President
January 30, 2006

1. Identification of the Device:
   Proprietary-Trade Name: Virtual Implant Placement™ (VIP) Dental Implant Surgery Planning Software
   Classification Name/Product Code: Picture archiving and communications system, 90 LLZ
   Common/Usual Name: Picture archiving and communications system

2. Equivalent legally marketed devices: ImplantMaster K042212 (I-Dent Ltd.) and SimPlant system, K033849, (Materialise.)

3. Indications for Use (intended use): This device employs previously scanned DICOM CT images in a software tool which serves as an aid to visualizing and pre-planning of dental implant surgery.

4. Description of the Device: Virtual Implant Placement, or simply VIP, is a software program that will allow dental implant clinicians to pre-plan their implant surgeries and/or to design surgical appliances that will be used during surgery. The program will presents the clinician with various reformatted CT images of their patient's jaw(s), allow the placement and manipulation of virtual implants, and provide measurement and other tools to assist the clinician. In typical usage a dentist evaluating a patient for dental implant surgery will often refer the patient for a CT scan to better visualize the patient's anatomy, and check the amount and density of the bone for its suitability for placing implants. The CT scan site will return the axial images from the CT scan on a CD in industry-standard DICOM format. Upon receipt of the CD, the doctor will "process" the case using VIP. Axial images are well-known to radiologists, but foreign to dentists. Processing involves the removal of unnecessary images which are outside the region of interest, and drawing a curve which will be used for the later reformatting of the data to produce images more familiar to dentists. After opening a disk of images, VIP will display the axial images and thumbnails of these, along with a scout view and a checklist of stops to follow in processing the case. After the case has been processed, the axial data will be processed to make panoramic images, which are parallel to the curve that was drawn during processing, and cross-sectional images, which are perpendicular to the panoramic image. Both types of images are normally generated by the Panorex machines dentists are familiar with. Since the primary purpose of VIP is to aid in the planning of implant surgeries, VIP will allow the surgeon to place simulated implants on the image and to gauge their size and position

relative to the surrounding anatomy. The simulated implants will be generic models of standard dental implants, which range from cylindrical to conical. When the data becomes available from various implant manufacturers, VIP will allow the user to pick from specific, currently-manufactured implants to approximately model any of their favorite implants.

5. Safety and Effectiveness, comparison to predicate devices:

Description	**SimPlant system, K033849, (Materialise.)**	**ImplantMaster K042212 (I-Dent Ltd.)**	**Virtual Implant Placement™ (VIP)**
Image Source	CT Scanner	DICOM CT	DICOM CT
Main indication	Indicated for use as a is a medical front-end software that can be used by medically trained people for the purpose of visualizing gray value images. It is indicated as a software interface and image segmentation system for the transfer of imaging information from a medical scanner such as a CT scanner or a Magnetic Resonance scanner. It is also indicated for use as a planning and simulation software for dental implant placement and surgical treatment	Uses DICOM CT data for visualization, diagnosis and treatment planning for dental implant surgery.	This device employs previously scanned DICOM CT images in a software tool which serves as an aid to visualizing and pre-planning of dental implant surgery.
Tools	Visualization, Implant placement, measurement of distances, angles and density	Visualization, Implant placement.	Visualization , Implant placement, Distance measurement, Angle measurement, Rectangular measurement, Elliptical measurement
Host platform	PC	PC	PC
Operating system	Not specified	Windows XP SP2 or Win 2000 SP4	Windows 98, 2000 and XP®
Host RAM	Not specified	512 Mb	256 MB RAM
Host Magnetic Storage	Not specified	1 GB	10 GB hard drive
CD ROM	Yes (for installation) or download	Yes (for installation)	Yes (for installation)
Host Processor Speed	Not specified	Intel P4 1.6 GHz (recommended: 2.8 GHz)	Pentium III, 500 MHz

6. Conclusion: In all important respects, the VIP is substantially equivalent to one or more predicate systems, including the one named above. This is based on testing to verify compliance with product specifications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 17 2006

Implant Logic Systems Ltd.
% Mr. Daniel Kamm, P.E.
Principal Consultant
Kamm & Associates
P.O. Box 7007
DEERFIELD IL 60015

Re: K060267
Trade/Device Name: Virtual Implant Placement™ (VIP)
Dental Implant Surgery Planning Software
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and
communications system
Regulatory Class: II
Product Code: LLZ
Dated: January 30, 2006
Received: February 1, 2006

Dear Mr. Kamm:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Virtual Implant Placement™ (VIP) Dental Implant Surgery Planning Software

Indications For Use:
This device employs previously scanned DICOM CT images in a software tool which serves as an aid to visualizing and pre-planning of dental implant surgery.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K060267